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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/560,539 04/28/00 CURTISS

R 3116-4355

EXAMINER

HM12/0803

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PORTNER, V

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

10
08/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/560,539

Applicant(s)

Curtiss et al

Examiner

Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 28, 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

Claims 1-38 are pending.

Election/Restriction

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 5, drawn to a microorganism that comprises a vector, an insertion site, first and second origins of replication, a first control sequence, and a first repressor, classified in class 935, subclass 72.
 - II. Claims 2-4, 6-8, 12-22 and 32-37, drawn to a microorganism that comprises a vector, first and second control sequences, a first repressor, a second repressor, a gene that encodes a desired product, and is attenuated , classified in class 435, subclass 69.3.
 - III. Claims 9-11 are, drawn to microorganisms that comprise a balance lethal host vector system, a vector, a desired gene product, a first and second control sequences, and first and second origins of replication, classified in class 435, subclass 481.
 - IV. Claims 23-31, drawn to a method of making a desired gene product, classified in class 935, subclass 60.
 - V. Claim 38 is, drawn to a method of delivering a desired gene product to a vertebrate, classified in class 935, subclass 107.

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2. Inventions Group I, II or III and Groups IV and Group V are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(I)).

3. Inventions Groups I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Group I has separate utility such as immunization for the microorganism alone, while Group II is able to induce an immune response to both the microorganism and the encoded desired gene product. The microorganisms of Group II can also be used as a source of producing the desired gene product in vitro. See MPEP § 806.05(d).

4. Inventions Groups II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Group III has separate utility such as an balanced lethal host vector system and lacks a functional essential gene and a recombinant functioning copy on the vector, wherein the microorganism will die upon activation of the lethal gene to product the environment upon release from the host, which is not a characteristic of the microorganisms of Group II. See MPEP § 806.05(d).

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention: Group II recites several species based upon various combinations of control sequences, repressor sequences, mutations to attenuate the microorganism and encoded desired gene product sequence.

Specific mutations to attenuate recited in claims 12 and 20 define species of microorganism. They are:

- | | |
|--------------|----------|
| a. Delta-end | g. A cdt |
| b. cya | h. hemA |
| c. crp | I. aroA |
| d. phoPQ | j. aroC |
| e. ompR | k. aroD |
| f. galR | l. hrtA |

Specific control sequences are recited in claims 5, 8, 14, 15, 16, 17, and 19 and define species of microorganism: They are:

araCPbab	P22Pr	Ptrc	Eukaryotic control.
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Specific repressor sequences are recited in claims 5, 14, 15, 16 and 17 and define species of microorganism: They are: LacI or C2.

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Specific origins of replication are recited in claims 13, 16 and 17 and define species of microorganism. They are: pSC ori and pUC ori.

Applicant is requested to elect a single combination from the now claimed microorganism for examination.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-4, 6, 19, 21 and 22 are generic.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 2, 2001


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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